REMARKS

Attached hereto is a Terminal Disclaimer to remove the obviousness-type double patenting rejection over U.S. Patent No. 6,030,845.

The Office Action raised an issue with regards to 35 U.S.C. Section 112 on Claim 9. Applicants appreciate the diligence of the Examiner in this matter and have clarified the typographical error wherein "reaction mixture" should have been "reaction product".

The Office Action also stated that Claim 9 was unclear as to what other element other than the hemolysis reagent was required in interpreting "adding the hemolysis reagent" step and the "hemolysing" step.

It is understood that by adding the hemolysis reagent, mixing it or integrating it with the whole blood sample, is part of the process. It is not necessary, however, to utilize an entirely different procedure, for example, freezing and thawing, or utilization of ultrasonic vibration, to break down the whole blood. It is believed that Claim 9 (Twice Amended) has now clarified this issue.

If there are any further questions with regards to this matter, the undersigned attorney would appreciate a telephone conference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on August 1, 2001.

By: Melissa Sanchez

Signature

Date: August 1, 2001

Respectfully submitted,

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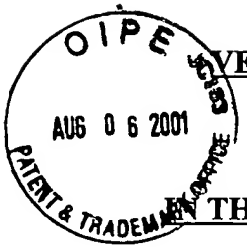

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claim 9 has been amended as follows:

9. (Twice Amended) An immunoassay method of quantifying a predetermined antigen in a sample of whole blood, comprising the steps of:

providing a sample of the whole blood;

adding a hemolysis reagent and a latex reagent directly to the sample of the whole blood[;] and hemolysing the whole blood sample with the hemolysis reagent to hemolyse the blood corpuscles;

reacting the hemolysed whole blood sample in an agglutination reaction to form a reaction [mixture] product wherein a predetermined antigen in the hemolysed whole blood sample specifically reacts with an antibody immobilized onto an insoluble carrier to provide [a] the reaction product;

irradiating the reaction product in the sample with radiation which includes a wavelength range which is substantially free from absorption by both hemoglobin and the hemolysis reagent; and

measuring only in the wavelength range which is substantially free from absorption by both hemoglobin and the hemolysis reagent, an absorbance of the incident radiation by the reaction product to determine the quantity of antigens in the sample.